

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BAXTER HEALTHCARE)	
CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 21-1184-CJB
)	
NEVAKAR INJECTABLES, INC.,)	
)	
Defendant.)	
)	
NEVAKAR INJECTABLES, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 21-1186-CJB
)	
BAXTER HEALTHCARE)	
CORPORATION,)	
)	
Defendant.)	

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MEMORANDUM OPINION

Dated: March 14, 2025
Wilmington, Delaware

Christopher J. Burke
BURKE, United States Magistrate Judge

Presently pending before the Court in these related patent litigation matters is a motion for summary judgment of non-infringement (“Motion”) of United States Patent Nos. 10,420,735 (the “735 patent”), 10,471,026 (the “026 patent”), 10,568,850 (the “850 patent”), 10,646,458 (the “458 patent”) and 11,602,508 (the “508 patent,” and collectively, the “patents-in-suit”) filed by Baxter Healthcare Corporation (“Baxter”) pursuant to Federal Rule of Civil Procedure 56. (Civil Action No. 21-1184-CJB, D.I. 126; Civil Action No. 21-1186-CJB, D.I. 125) The Motion is opposed by Nevakar Injectables, Inc. (“Nevakar”). For the reasons set forth below, the Motion is GRANTED-IN-PART and DENIED-IN-PART.¹

I. BACKGROUND

A. Procedural Background

The parties commenced the respective actions on August 18, 2021. (Civil Action No. 21-1184-CJB, D.I. 1; Civil Action No. 21-1186-CJB, D.I. 1) In Civil Action No. 21-1184-CJB, Baxter (Plaintiff in that case) currently seeks, *inter alia*, a declaratory judgment that its Norepinephrine Bitartrate in 5% Dextrose Injection, 0.016 mg/mL and 0.032 mg/mL products (“Baxter’s products” or the “products at issue” or the “accused products”) do not infringe each of the five patents-in-suit. (Civil Action No. 21-1184-CJB, D.I. 99) In Civil Action No. 21-1186-

¹ The parties have jointly consented to the Court’s jurisdiction to conduct all proceedings in these cases, including trial, the entry of final judgment and all post-trial proceedings. (Civil Action No. 21-1184-CJB, D.I. 39; Civil Action No. 21-1186-CJB, D.I. 37)

CJB, Nevakar, the patentee (and Plaintiff in that case),² alleges that Baxter's products infringe each of the patents-in-suit. (Civil Action No. 21-1186-CJB, D.I. 97)³

The Court held a *Markman* hearing on November 15, 2022. (Civil Action No. 21-1184-CJB, D.I. 86; Civil Action No. 21-1186-CJB, D.I. 84) On June 26, 2023, the Court issued its Memorandum Order on claim construction ("Claim Construction MO"). (Civil Action No. 21-1184-CJB, D.I. 106; Civil Action No. 21-1186-CJB, D.I. 106) Thereafter, the parties stipulated to a stay in this case so that Baxter could file the instant Motion; with the Motion, Baxter seeks summary judgment of non-infringement of the patents-in-suit, premised on the Court's construction of the claim term "chelating agent" (as set forth in the Claim Construction MO). (Civil Action No. 21-1184-CJB, D.I. 125; Civil Action No. 21-1186-CJB, D.I. 124)

Baxter filed the instant Motion on October 18, 2023. (Civil Action No. 21-1184-CJB, D.I. 126; Civil Action No. 21-1186-CJB, D.I. 125) The Motion was fully briefed as of January 16, 2024. (Civil Action No. 21-1184-CJB, D.I. 144; Civil Action No. 21-1186-CJB, D.I. 143) The Court heard oral argument on the Motion on February 7, 2024. (Civil Action No. 21-1184-CJB, D.I. 155 (hereafter, "Tr."); Civil Action No. 21-1186-CJB, D.I. 154)

² Par Sterile Products, LLC ("Par") and Endo Ventures Ltd. ("Endo") were originally Plaintiffs in Civil Action No. 21-1186-CJB and Defendants in Civil Action No. 21-1184-CJB, along with Nevakar. Baxter and Nevakar eventually stipulated in these actions to voluntarily dismiss Endo and Par and to maintain the two actions as between Baxter and Nevakar. (Civil Action No. 21-1184-CJB, D.I. 90 at 3-4; Civil Action No. 21-1186-CJB, D.I. 88 at 3-4)

³ The respective suits initially included claims regarding one or both of two additional patents—U.S. Patent Nos. 10,159,657 (the "'657 patent") and 10,226,436 (the "'436 patent"); however, the '657 and '436 patents were subsequently dismissed without prejudice. (See, e.g., Civil Action No. 21-1184-CJB, D.I. 1, D.I. 57; Civil Action No. 21-1186-CJB, D.I. 1, D.I. 56)

B. Factual Background⁴

The patents-in-suit⁵ are generally directed to “compositions and methods for ready-to-inject norepinephrine compositions with improved stability.” (See, e.g., '735 patent, Abstract) The inventions described therein are said to address the “need for improved stable, low concentration, ready-to-inject and antioxidant free norepinephrine formulations, and methods of manufacturing and storing the same.” (Id., col. 3:45-48)

The parties have treated claim 1 of the '735 patent as an exemplary claim for our purposes, (Tr. at 13), and that claim recites as follows:

1. A method of treating hypotension, comprising:

administering a ready-to-administer norepinephrine composition at an initial dose per minute;

administering the norepinephrine composition at a maintenance dose per minute, wherein the initial dose per minute is greater than the maintenance dose per minute;

wherein the initial dose per minute is a dose of between 8 and 12 µg/min, and wherein the maintenance dose per minute is a dose of between 2 and 4 µg/min;

wherein the norepinephrine composition comprises norepinephrine or a salt thereof at a concentration of between 10 µg/ml and 100 µg/ml in an aqueous acidic solution having a pH range of between 3.7 and 4.3, wherein the aqueous acidic solution further comprises a *chelating agent* at a concentration of between 1 µg/ml and 100 µg/ml and a tonicity agent;

wherein the norepinephrine composition is substantially free of antioxidants; and

⁴ For ease of reference, from here on out, the Court will cite to the docket entries in Civil Action No. 21-1184-CJB, unless otherwise noted.

⁵ The patents-in-suit are located in various places on the docket, including as exhibits 2-6 in D.I. 129. Hereafter, the Court will simply cite to the patent numbers.

wherein the norepinephrine or a salt thereof in the norepinephrine composition comprises at least about 90% R-isomer of norepinephrine after storage at 25±2° C. and 60±5% relative humidity, over at least three months as determined by HPLC.

('735 patent, col. 21:35-58 (emphasis added))

To the extent additional facts are relevant to resolution of the Motion, they will be set out in Section III.

II. STANDARD OF REVIEW

A. Summary Judgement

Summary judgment is appropriate where “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585 n.10 (1986). If the moving party has sufficiently demonstrated the absence of such a dispute, the nonmovant must then “come forward with specific facts showing that there is a genuine issue for trial.” *Id.* at 587 (internal quotation marks, citation and emphasis omitted). If the nonmoving party fails to make a sufficient showing in this regard, then the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, the Court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

However, in order to defeat a motion for summary judgment, the nonmoving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co.*, 475 U.S. at 586. The “mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary

judgment; the requirement is that there be no *genuine* issue of *material* fact.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). Facts that could alter the outcome are “material,” and a factual dispute is “genuine,” only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* at 248. “If the evidence is merely colorable . . . or is not significantly probative . . . summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted).

A party asserting that a fact cannot be—or, alternatively, asserting that a fact is—genuinely disputed must support the assertion either by “citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials;” or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B).

B. Patent Infringement

The patent infringement analysis consists of two steps. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must determine the meaning and scope of the patent claims asserted to be infringed. *Id.* Claim construction is generally a question of law, although subsidiary factfinding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326-27 (2015). Second, the trier of fact must compare the properly construed claims to the allegedly infringing product. *Markman*, 52 F.3d at 976. This second step is a question of fact. *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012).

“Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device.” *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). If any claim limitation is absent from the accused product, there is no literal infringement as a matter of law. *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). Additionally, a product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents (“DOE”) if any differences between the claimed invention and the accused product are insubstantial. *See VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1322 (Fed. Cir. 2014). The patent owner (here, Nevakar) has the burden of proving infringement, and must do so by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

When an accused infringer (here, Baxter) moves for summary judgment of non-infringement, such relief may be granted only if at least one limitation of the asserted claim does not read on an element of the accused product, either literally or under the DOE. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *see also TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002) (“Summary judgment of noninfringement is [] appropriate where the patent owner’s proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial.”).

Therefore, the court may grant summary judgment of non-infringement only if, after viewing the facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused product is covered by the claims, as construed by the Court. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999).

III. DISCUSSION

With its Motion, Baxter seeks summary judgment of non-infringement on all asserted claims of the patents-in-suit as to Nevakar's claims of literal direct infringement, direct infringement under the DOE and indirect infringement. The Court will address the Motion as it relates to each claim type at issue.

A. Literal Direct Infringement

The Court first addresses Baxter's Motion to the extent it seeks summary judgment of non-infringement regarding Nevakar's claims of literal direct infringement.

As was noted above with regard to claim 1 of the '735 patent, each of the asserted claims of the patents-in-suit requires a "ready-to-administer norepinephrine composition"⁶ that comprises specific ingredients, one of which is "norepinephrine [or a salt thereof]" and another is a "chelating agent." (D.I. 127 at 7-9 (listing exemplary independent asserted claims from each of the patents-in-suit); D.I. 128 at ¶¶ 5-11) In its Claim Construction MO, the Court set out, in some detail, the reasons supporting its conclusion that "chelating agent" should be construed to mean "a separate chemical compound, added to the composition." (D.I. 106 at 4-12, 15)⁷ The Court also explained therein why it rejected Nevakar's contrary argument that a chelating agent

⁶ The Court has construed "norepinephrine" to mean "norepinephrine or pharmaceutically acceptable salts (e.g., norepinephrine bitartrate) or prodrugs thereof." (D.I. 106 at 33)

⁷ For example, one of the many reasons why the Court came to this conclusion was that: (1) the parties had agreed that the "chelating agent" term meant the same thing as used in all of the patents-in-suit; and (2) certain of the asserted method claims involve "admixing" or "combining" norepinephrine or a salt thereof, a chelating agent and other ingredients. (*Id.* at 8 (citing '026 patent, col. 20:31-33, '458 patent, col. 20:44-46)) The Court reasoned that "[u]sing terms like 'admixing' and 'combining' in this way signals that the 'chelating agent' is an entirely separate chemical compound as compared to the other ingredients with which it is being 'admix[ed]' or 'combin[ed]' into the solution—including 'norepinephrine or a salt thereof.'" (*Id.* (citation omitted); *see also* Tr. at 46-47)

could be a substance that is initially part of the claimed norepinephrine or norepinephrine salt and then is liberated from the norepinephrine substance when that substance is placed in the claimed aqueous solution. (*Id.* at 4-12, 15)⁸

In light of the Court’s claim construction of “chelating agent,” Baxter argues that it is entitled to summary judgment of non-infringement as to Nevakar’s claims of literal direct infringement. Baxter says this is so because it is undisputed that its products do not comprise a chelating agent that is “a separate chemical compound, added to the [claimed] composition.” (D.I. 127 at 10) Baxter emphasizes that there can be “no dispute” on this point, in part because:

⁸ Prior to the *Markman* hearing, Baxter had proposed that the construction for chelating agent should also include the limitation “at least two donor groups that form a ring structure with a metal ion.” (D.I. 106 at 5 n.6) In its claim construction briefing, Nevakar seemed to suggest that it did not oppose this portion of Baxter’s construction. (*Id.*) But then at the *Markman* hearing, Nevakar indicated for the first time that it *did* dispute this language; its counsel then offered new arguments as to why the proposed addition was incorrect. (*Id.*; D.I. 144 at 6) In its Claim Construction MO, the Court advised the parties that it would not address the dispute at that time; it explained that if the dispute lingered, the parties could jointly advise the Court of this by no later than the deadline for submission of summary judgment briefing. (D.I. 106 at 5 n.6)

Unfortunately, the parties did not do that in advance of the instant briefing here on summary judgment. In that briefing, Baxter again proposed that the construction for this term should include the phrase “with at least two donor groups that form a ring structure with a metal ion[,]” (D.I. 144 at 6), while Nevakar suggested that term should additionally be construed to mean “a compound containing donor atoms that can combine by coordinate bonding with metal ions to form a cyclic structure called a chelating complex, or simply, a chelate[,]” (D.I. 134 at 3).

At the hearing on the Motion, however, both sides confirmed that: (1) they could not identify any meaningful difference between their competing constructions, such that it is not clear that the parties actually have a live dispute about claim scope on this front; and (2) the outcome of the Motion would not be impacted by the resolution of this additional claim construction dispute (if it is even a dispute). (D.I. 144 at 8; Tr. at 18-19, 41-42) For these reasons, then, the Court declines to further construe “chelating agent” at this time. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (noting that “only those terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy”).

(1) when it filed its New Drug Application with the United States Food and Drug Administration, it did not identify a separate chelating agent that is added to the composition as part of the method of making its products; and (2) its labeling for the products does not state that the products comprise such a chelating agent. (*Id.* at 10-11; D.I. 128 at ¶¶ 24-25; D.I. 129, exs. 10-13, 15) Baxter explains that Nevakar’s literal direct infringement theory is that the chelating agent in Baxter’s accused products is “the ‘norepinephrine’ (i.e., the active ingredient)—specifically, the bitartrate anions that may dissociate[from the active ingredient]—when in solution” (hereafter, Nevakar’s “dissociated bitartrate anions” theory). (D.I. 127 at 12; *see also* Tr. at 6) And it asserts that this theory is foreclosed by the Court’s claim construction for “chelating agent.” (D.I. 127 at 12-13)

During the hearing on the Motion, Nevakar’s counsel essentially acknowledged that Baxter is correct—i.e., that in light of the construction for “chelating agent”—Nevakar cannot make a viable argument of literal direct infringement. (Tr. at 39); *see also Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1363 (Fed. Cir. 2019) (noting that “[w]here the parties do not dispute any relevant facts regarding the accused product[,] but disagree over possible claim interpretations, the question of literal infringement collapses into claim construction and is amenable to summary judgment”) (internal quotation marks and citation omitted).⁹ To that end, Nevakar’s counsel explained:

If the claim construction means that the [accused] chelating agent, the tartrate, has to be added separately from the norepinephrine, then obviously, we’re not going to be able to show literal infringement. . . . So if the norepinephrine and bitartrate have to

⁹ Indeed, as Baxter points out, Nevakar had made similar admissions prior to the *Markman* hearing (i.e., to the effect that if the Court adopted Baxter’s proposed construction for “chelating agent,” there could be no literal direct infringement here). (D.I. 127 at 13 (citing D.I. 67 at 6))

be separate at the time they're added to the composition, again, reserving all rights to appeal . . . we can concede on that and we can move along here and focus on doctrine of equivalents.

(Tr. at 38-39)¹⁰

¹⁰ In its Motion briefing, Nevakar did make an argument as to why summary judgment of non-infringement should be denied as to its claim of literal direct infringement of the '508 patent (i.e., one of the five patents-in-suit). There, Nevakar argued that the Court's claim construction for "chelating agent" might need to be different regarding that term's use in the '508 patent—as compared to the other four patents-in-suit—because: (1) the '508 patent had not yet issued at the time of the *Markman* hearing in this case; and (2) the '508 patent claims include unique language that required such a result. (D.I. 134 at 5-6) During the Motion hearing, the Court pressed Nevakar's counsel on this point. In response, Nevakar's counsel conceded that—in light of the Court's claim construction decision as to "chelating agent"—Nevakar was withdrawing this assertion. (Tr. at 44-46) And so the Court considers any such argument to have been conceded here.

That said, even had the argument not been conceded, the Court would have rejected it for three reasons.

The first relates to a question of timing. Although the '508 patent had not issued at the time of the *Markman* hearing (held in November 2022), it did issue in March 2023, (D.I. 129, ex. 6); allegations regarding alleged infringement of the '508 patent were thereafter added to the operative complaints in these cases by April 2023, (*see, e.g.*, D.I. 99). So by the time the Court issued the Claim Construction MO in June 2023, the '508 patent was in the case (indeed, the Court noted this fact in the Claim Construction MO). (D.I. 106 at 1-2) And yet at no point prior to the issuance of the Claim Construction MO did Nevakar tell the Court that any claim construction arguments it had made in the *Markman* briefing or at the *Markman* hearing would differ, in light of the fact that the '508 patent was now in the case. (D.I. 144 at 8; Tr. at 12) Nevakar's failure to earlier raise any such argument regarding the '508 patent's claims in this context seems an indication that there *was no good argument* to make on that front—and that any belated assertion to the contrary was really just a way of re-arguing claim construction, (D.I. 144 at 9). That should not be permitted here.

Second, prior to and during the *Markman* hearing, all parties had agreed that claim 1 of the '735 patent was a representative claim that could be used to assess claim construction arguments as to all of the then-existing patents-in-suit. (*See* D.I. 106 at 3-4, 16, 21, 24) Those then-existing patents-in-suit included the '850 patent. Like the '508 patent, the '850 patent has independent claims that are composition claims, and the '850 patent shares a substantially similar specification and similar claims to the '508 patent. (Tr. at 12, 15-16; D.I. 86 at 51; D.I. 134 at 9-11; D.I. 144 at 8-9) Nevakar has not credibly explained why, if the relevant claims of the '850 patent are similar to the claims of the other patents-in-suit, then the '508 patent's like claims should not be viewed the same way.

Therefore, in light of the Court’s construction of “chelating agent” and the evidence before it, the Court grants Baxter’s Motion to the extent it seeks summary judgment of non-infringement as to Nevakar’s claims of literal direct infringement.

B. DOE

Next, the Court addresses the Motion to the extent it seeks summary judgment of non-infringement as to Nevakar’s claims of direct infringement under the DOE. In support, Baxter makes two primary arguments. First, it asserts that Nevakar’s arguments fail under the “all-elements” rule, because accepting Nevakar’s DOE position would vitiate the “chelating agent” claim limitation. (D.I. 127 at 14-15) Second, Baxter states that Nevakar’s arguments fail under the “specific exclusion” rule. (*Id.* at 15-16)

Below, the Court will first set out some relevant general legal standards regarding the DOE. Thereafter, it will address Baxter’s arguments in turn. In doing so, it will explain why they are insufficient to permit summary judgment and why the Motion must be denied on this ground.

1. Legal Standards

“Even when an accused product does not meet each and every claim element literally, it may nevertheless be found to infringe the claim if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention.” *Intendis*

Third, applying the Court’s construction for “chelating agent” to the term’s use in the ‘508 patent comports with Federal Circuit law and the law in this District. That law notes that “[w]here multiple patents derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents.” *SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1316 (Fed. Cir. 2015) (internal quotation marks and citation omitted); *see also Bioverativ Inc. v. CSL Behring LLC*, Civil Action No. 1:17-cv-00914-RGA, 2019 WL 1276030, at *4 (D. Del. Mar. 20, 2019).

GmbH v. Glenmark Pharms. Inc., USA, 822 F.3d 1355, 1360 (Fed. Cir. 2016) (certain internal quotation marks and citations omitted). The DOE is applied to individual elements of the claim, not to the invention as a whole. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997).

There are two frameworks for establishing equivalence: (1) the function-way-result (“FWR”) test; and (2) the “insubstantial differences” test. *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 866-67 (Fed. Cir. 2017). “To succeed on a [DOE] theory, the patentee must demonstrate equivalence under one of these two tests.” *Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1347 (Fed. Cir. 2013). The FWR test requires the patentee “to show, for each claim limitation, that the accused product ‘performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product.’” *Id.* (citation omitted). The insubstantial differences test asks whether the accused product or process is substantially different from what is patented. *Mylan Institutional LLC*, 857 F.3d at 866.

However, a patentee’s use of the DOE has its limits. Two of those limits relate to Baxter’s invocation of the “all elements” rule and the “specific exclusion” rule. And so the Court will address those concepts in more detail below, as it confronts Baxter’s arguments as to each.

2. Discussion

a. The “all-elements” rule and vitiation

Baxter’s first argument is that “the ‘all-elements rule[] specifically applies here and forecloses Nevakar’s attempt to use the [DOE] to avoid the *Markman* Order[’s]” construction of “chelating agent.” (D.I. 127 at 14) “Under the all-elements rule, an accused product or process

is not infringing unless it contains each limitation of the claim, either literally or by an equivalent.” *PSN Ill., LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1167-68 (Fed. Cir. 2008) (internal quotation marks and citation omitted).

In invoking the all-elements rule, Baxter is really getting at the concept of “vitiation.” In that regard, the United States Court of Appeals for the Federal Circuit has explained that the DOE must not expand so far as to eliminate a claim element entirely, *see Warner-Jenkinson Co.*, 520 U.S. at 29, and thus that an element of a product or process cannot, as a matter of law, be equivalent to a limitation of the claimed invention if such a finding would “entirely vitiate the limitation[,]” *PSN Ill., LLC*, 525 F.3d at 1168 (internal quotation marks and citation omitted). Vitiation itself is not an exception to the DOE; instead, it is a legal determination that the “the evidence is such that no reasonable jury could determine two elements to be equivalent.” *Brilliant Instruments, Inc.*, 707 F.3d at 1347 (internal quotation marks and citation omitted); *see also Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1371-72 (Fed. Cir. 2015). “[V]itiation applies when one of skill in the art would understand that the literal and substitute limitations are not interchangeable, not insubstantially different, and when they do not perform substantially the same function in substantially the same way, to accomplish substantially the same result.” *Brilliant Instruments, Inc.*, 707 F.3d at 1347. In other words, “saying that a claim element would be vitiated is akin to saying that there is no equivalent to the claim element in the accused device based on the well-established ‘function-way-result’ or ‘insubstantial differences’ tests.” *Id.* To determine whether finding infringement under the DOE would vitiate a claim limitation, courts consider the totality of circumstances. *PSN Ill., LLC*, 525 F.3d at 1168.

With the relevant law on vitiation now set out, the Court turns back to Nevakar’s infringement position under the DOE (and Baxter’s argument for summary judgment related

thereto). Here we'll start with the facts relating to Baxter's products at issue. Such facts are set out in a declaration provided by Nevakar's expert Dr. Bradley Anderson, which Nevakar filed along with its answering brief. Dr. Anderson's declaration explains the following:

- Baxter's products are made using the following compounds: (1) norepinephrine bitartrate monohydrate, (2) dextrose monohydrate, (3) sodium hydroxide and/or hydrochloric acid, and (4) water for injection. (D.I. 136 ("Anderson Decl.") at ¶¶ 46-47 (citations omitted))
- There is no separate chelating agent used to make the Baxter products. Instead, the norepinephrine bitartrate salt is added to the aqueous solution, and when this happens, the substance *dissociates* into norepinephrine (i.e., the component providing therapeutic efficacy) *and a separate tartrate species*; these ions (the norepinephrine ions on the one hand, and those of the tartrate species on the other) are separate and independent chemical compounds as they reach the bulk solution, and thereafter, they diffuse independently into the rest of the solution. (*Id.* at ¶¶ 51-53)
- Depending on the pH of the bulk solution, it is possible that additional tartrate species will be present. (*Id.* at ¶ 53) The tartrate species that are present "will bind with metal ions in Baxter's [p]roducts and form chelates." (*Id.* at ¶¶ 53-54; *see also id.* at ¶¶ 55-56)

From there, Nevakar asserts that there is a genuine dispute of fact as to whether the dissociated bitartrate anions (i.e., the separate tartrate species referenced above in Dr. Anderson's declaration) in Baxter's products are equivalent to the claimed "chelating agent." Nevakar argues that, under both the FWR test and the insubstantial differences test, the dissociated bitartrate anions *are* equivalent to a separately-added chelating agent. In support of this position, Dr. Anderson provides the following additional statements in his declaration:

- "The term 'chelating agent' is commonly understood as a compound containing donor atoms that can combine by coordinate bonding with metal ions to form a cyclic structure called a chelating complex, or . . . a chelate." (*Id.* at ¶ 35)

- When considered in the context of liquid pharmaceutical formulations, chelating agents control and sequester metal ions that might be present in a solution, and the chelating agent prevents these ions from reacting with other compounds that might be present in the solution and cause them to degrade. (*Id.*)
- One well-known chelating agent is tartaric acid. (*Id.* at ¶ 37 (citations omitted)) Tartaric acid is one of three species of tartrate that could be present in a solution, depending on the pH of the solution; the other two are bitartrate and tartrate. (*Id.* at ¶ 39)
- A person of ordinary skill in the art (“POSITA”) would understand that any of the three tartrate species may be present in a solution, and reference to one would signify the presence of the others depending on the pH of the solution. (*Id.* at ¶ 40)
- The tartrate species are capable of forming chelates with metal ions at multiple sites on the molecule, and in various different ways. (*Id.* at ¶ 41)
- “From a scientific perspective, whether the bitartrate anion is added to the solution as an independent chemical compound, or whether it starts as part of the norepinephrine bitartrate salt, dissolves and separates (dissociates) in the solution makes no practical difference to its ability to chelate—that is to bind with and sequester metal ions that might be present in the solution by forming rings with them.” (*Id.* at ¶ 44)
- In pharmaceutical chemistry, it is not uncommon for a single ingredient to perform more than one function in a composition (particularly as to ingredients that are salts, since salts consist of two or more molecules that are joined by ionic bonds that break when the salt dissolves, after which each molecule is separate from each other and can then perform its own function in solution). (*Id.* at ¶ 45)

With all of the above set out, in paragraph 64 of his report, Dr. Anderson then articulates his view that Baxter’s products perform substantially the same function (i.e., chelating) in substantially the same way (i.e., forming a ring structure by reacting with metal ions) in order to achieve substantially the same result (i.e., scavenging metal ions that can cause oxidation of the

active pharmaceutical ingredient) as that called for by the asserted claims. (*Id.* at ¶ 64¹¹; *see also* D.I. 134 at 6-7) And in paragraph 65 of his report, Dr. Anderson also asserts that whether the tartrate species dissociates from the norepinephrine or is added independently to the solution amounts to an “insubstantial difference[,]” because it “makes no difference at all to the chelating function of a chelating agent (how it chelates and how well it chelates) whether [the chelating agent] is added separately or not.” (Anderson Decl. at ¶ 65; *see also id.* at ¶¶ 67-86 (explaining how the above-referenced analysis relates to alleged infringement of each of the asserted claims of the patents-in-suit); *see also* D.I. 134 at 7)

The evidence put forward by Dr. Anderson is sufficient to create a genuine dispute of material fact on the question of whether the bitartrate anions in Baxter’s products are equivalent to the claimed chelating agent, pursuant to both of the relevant DOE-related tests. A reasonable fact finder could side with Dr. Anderson and Nevakar on these points; if it did, then Nevakar’s position could win the day as to direct infringement under the DOE.

Baxter pushes back on this conclusion by making three specific counterarguments. (D.I. 127 at 14-18) The Court will address these below in turn, explaining why none win the day.

First, in its opening brief, Baxter put forward its vitiation argument—i.e., it asserted that if Nevakar’s position were correct, this would entirely “vitiate . . . the ‘chelating agent’ limitation altogether and render it meaningless.” (D.I. 127 at 14; *see also* D.I. 144 at 11) Baxter said that this is so because Nevakar’s DOE infringement position would effectively “eliminat[e]” the “chelating agent” claim element and would render that element “hardly necessary[—]since the

¹¹ The Court here cites to a section of Dr. Anderson’s report that relates to a discussion of claim 1 of the '735 patent, which, as the Court previously noted above, the parties are treating as representative of other asserted claims of the other asserted patents, for purposes of this Motion. *See supra* at 11 n.10.

‘norepinephrine’ would alone suffice[to provide the chelating agent to the claimed composition].” (D.I. 127 at 14) During oral argument, Baxter’s counsel further explained its position. Counsel stated that because Nevakar’s DOE argument implicates a circumstance (i.e., that the bitartrate anions in the Baxter products were once a part of the products’ norepinephrine component) that is essentially the opposite or the antithesis of the Court’s claim construction for “chelating agent” (i.e., that the chelating agent must be a “separate chemical compound, added to the overall composition”), then the Court did not even “hav[e] to look at” Dr. Anderson’s proffered evidence, nor “undertake [any] analysis” of that evidence pursuant to the FWR test or insubstantial differences test. (Tr. at 81-82)

Nevakar responds that Baxter has the law exactly wrong. Instead, it asserts that Federal Circuit caselaw is clear that when a claim of vitiation is made, a court does not simply ask “Does the DOE argument seem like it relies on the opposite of what the claim construction for a term requires?” Instead, Nevakar explains that even when faced with a vitiation argument from the accused infringer, the Court must “still [] do the work of [applying] the actual, factual [FWR] test or insubstantial differences test”—in order to determine whether summary judgment should be granted as to a DOE infringement theory. (Tr. at 75-76; *see also id.* at 59-60; Nevakar’s Hearing Presentation, Slide 12)

The Court agrees with Nevakar. Most helpful to the Court’s analysis here was a line of Federal Circuit cases best represented by *Cadence Pharms. Inc. SCR v. Exela Pharmsci Inc.*, 780 F.3d 1364 (Fed. Cir. 2015). In *Cadence*, the Federal Circuit upheld a district court’s finding of infringement under the DOE. 780 F.3d at 1370. The district court concluded that the relevant asserted claim required that—as to the claimed step of “deoxygenation of the solution”—that the active ingredient must be dissolved in a solution *before* deoxygenation. *Id.* But the plaintiff’s

DOE infringement position was that the defendant's accused process infringed when the active ingredient was added and dissolved *after* the solution had been deoxygenated. *Id.* On appeal, the defendant argued that the district court erred in finding that its process infringed under the DOE. It asserted that accepting the plaintiff's DOE argument would vitiate the "deoxygenation" claim limitation—in that "deoxygenating after adding the active ingredient is the 'antithesis' of deoxygenating before adding the active ingredient[.]" *Id.* at 1371.

However, the *Cadence* Court firmly disagreed, noting that the defendant "fundamentally misunderstands the doctrine of claim vitiation." *Id.* The Federal Circuit went on:

"Vitiation" is not an exception or threshold determination that forecloses resort to the doctrine of equivalents, but is instead a legal conclusion of a lack of equivalence based on the evidence presented and the theory of equivalence asserted. We have repeatedly reaffirmed this proposition. . . . *Characterizing an element of an accused product as the "antithesis" of a claimed element is also a conclusion that should not be used to overlook the factual analysis required to establish whether the differences between a claimed limitation and an accused structure or step are substantial vel non. The determination of equivalence depends not on labels like "vitiation" and "antithesis" but on the proper assessment of the language of the claimed limitation and the substantiality of whatever relevant differences may exist in the accused structure.*

Id. at 1371-72 (emphasis added) (internal citations omitted). And the Federal Circuit has, in cases like *Bio-Rad Lab'ys Inc. v. 10X Genomics Inc.*, 967 F.3d 1353 (Fed. Cir. 2020), thereafter continued to affirm that "vitiation is not an exception or threshold determination that forecloses resort to the [DOE], but is instead a legal conclusion of a lack of equivalence based on the evidence presented and the theory of equivalence asserted." 967 F.3d at 1367-68 (internal quotation marks and citations omitted) (emphasis added) (rejecting the assertion that because the alleged equivalent was said to be "diametrically opposed" to the missing claim element, this meant that the DOE inquiry was at an end—and emphasizing that a court must still engage in an

analysis as to “whether a reasonable juror could [find that the proposed equivalent] performs the same function, in the same way, and achieves the same result” as the claim element); *see also Edgewell Pers. Care Brands, LLC v. Munchkin, Inc.*, 998 F.3d 917, 923-25 (Fed. Cir. 2021).¹²

In this case, it could well be said (as Baxter argues) that the Court’s construction of “chelating agent” to mean a “separate chemical compound, added to the overall composition” sounds like the antithesis of, or the opposite of, the way that the chelating agent is present in Baxter’s products. After all, the bitartrate anions in Baxter’s products are *not* separately added to the solution vis-à-vis other claimed components like norepinephrine—they started out as part of the norepinephrine substance in the first place. But in line with the Federal Circuit’s guidance in cases like *Cadence*, that type of “antithesis” or “opposite” argument is not the end of the DOE/“vitiation” inquiry. Instead, the Court must go on to assess the “substantiality” of Nevakar

¹² The Court acknowledges that, as Baxter suggests, (D.I. 127 at 15; Tr. at 29, 32, 79), there are other (typically older) Federal Circuit opinions that speak to the vitiation doctrine and that, at least facially, do seem to focus on whether the asserted equivalent is the “antithesis” of the claimed requirement—without necessarily discussing in great detail how the record evidence regarding the FWR test or the insubstantial differences test contributed to a conclusion that there could be no finding of infringement under the DOE. *See, e.g., Novartis Pharm. Corp. v. Eon Labs Mfg., Inc.*, 363 F.3d 1306, 1312 (Fed. Cir. 2004) (“Here the formation of a particulate dispersion inside the body cannot infringe under the [DOE] because this would vitiate the claimed requirement that the dispersion be prepared outside the body. . . . To extend the scope of the claims at issue to encompass a dispersion formed inside the stomach would necessarily read the ‘hydrosol’ limitation out of those claims.”) (citation omitted); *see also Planet Bingo, LLC v. GameTech Int’l, Inc.*, 472 F.3d 1338, 1344-45 (Fed. Cir. 2006) (“In this case, the proposed application of the [DOE] would change ‘before’ to ‘after,’ a more marked difference [than in prior cases]. This court has refused to apply the doctrine in other cases where the accused device contained the antithesis of the claimed structure.”). But however one might read those earlier cases, the Court understands the Federal Circuit’s later decisions in cases like *Cadence* and *Bio-Rad* as emphasizing that the caselaw *should* be read as confirming that the vitiation inquiry does not turn solely or primarily on a linguistic assessment of whether an asserted equivalent is the “antithesis” of or the “opposite” of (or would “eliminate”) a claim limitation at issue. *See, e.g., Cadence*, 780 F.3d at 1371 (distinguishing *Planet Bingo* as a case where the “holding was based on a finding that a combination determined before a game was substantially different, factually, from a combination determined after the game started”).

and Dr. Anderson's evidence regarding the FWR or insubstantial differences tests—in order to determine whether summary judgment is warranted.

With its second counterargument, Baxter criticizes the substance of that very evidence. There Baxter asserts that—even were the Court to consider it—Dr. Anderson's declaration cannot create a genuine issue of material fact. On that score, Baxter points to paragraph 54 of Dr. Anderson's declaration, wherein Dr. Anderson opines “that any dissociated bitartrate anion present in Baxter's products ‘will’ chelate”; Baxter faults Dr. Anderson for relying therein only on a citation to “a 1947 article that discusses ferric tartrate and ferric citrate complexes formed in solutions and conditions different from those in Baxter's products.” (D.I. 144 at 13 (citing Anderson Decl. at ¶ 54 & ex. E)) Baxter also argues that Dr. Anderson's position that the bitartrate anion in the accused products will chelate is contradicted by: (1) “his other exhibits, which report that by the 1980s, tartaric acid was understood to be a ‘buffer’ and ‘often ineffective’ at chelating[,]” (*id.* (citing Anderson Decl., ex. B at BAXNOR_0007505, BAXNOR_0007510)); and (2) the “common specification and Nevakar's Product, [which] further confirm that tartrate anions in norepinephrine bitartrate aqueous solutions do not chelate[,]” (*id.* at 13-14).

The Court again disagrees with Baxter here. With regard to the 1947 article, Mr. Anderson seems simply to have referenced it to note one example of how a tartrate can serve a chelating function. (Tr. at 72) And Dr. Anderson went beyond that citation in his declaration—in that he also further explained: (1) how bitartrate anions like those in the accused Baxter products are capable of forming chelates with metal ions; and thus (2) why it can be understood that the bitartrate anions *in Baxter's products* would have those same capabilities when in solution. (Anderson Decl. at ¶¶ 39-41, 53-56, 62; Tr. at 84) Additionally, the fact that other

evidence of record (like the content of certain exhibits that Dr. Anderson cites to, or a portion of the common specification) might suggest a different conclusion than what Dr. Anderson proposes is not a reason to grant summary judgment. It is simply underscores that there is a material dispute of fact on the point, which should be explored at trial. *See e.g., Spring Commc'ns Co. LP v. Charter Commc'ns, Inc.*, C.A. No. 17-1734-RGA, 2021 WL 982732, at *3-4 (D. Del. Mar. 16, 2021) (finding that there was a genuine dispute of fact precluding summary judgment as to the plaintiff's DOE theory, where although the defendant cited to evidence in its favor—such as by pointing to the plaintiff's prior descriptions of the invention, and by arguing that the plaintiff's position would vitiate a particular claim limitation—the plaintiff's expert provided a detailed FWR analysis, which explained why certain media gateways in defendant's product were the equivalent to the claimed ATM interworking multiplexer); *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, Civil Action No. 11-515-LPS-CJB, 2015 WL 12806483, at *11 (D. Del. Apr. 21, 2015) (finding a that a material issue of fact precluded summary judgement of non-infringement under the DOE, despite the defendant's assertion that the plaintiff's infringement theory vitiated a particular claim limitation, where the parties offered conflicting expert evidence regarding the applicability of the FWR test) (citing *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1314-15 (Fed. Cir. 2009)), *report and recommendation adopted*, 2015 WL 3622897 (D. Del. June 9, 2015).

Baxter's third and final counterargument is that Dr. Anderson's declaration fails to acknowledge that the asserted claims require a norepinephrine composition with a *specific concentration* of the chelating agent. (D.I. 144 at 14 (citing '735 patent, claim 1, which includes a requirement that the chelating agent be at a concentration of "between 1 μ g/ml and 100 μ g/ml")) Here Baxter argues that even if Dr. Anderson had sufficiently established that "any

dissociated bitartrate anions in Baxter’s products *will* chelate, he failed to establish that those dissociated bitartrate anions are also present at the *claimed concentrations*.” (*Id.* (certain emphasis added, certain emphasis in original); *see also* Tr. at 14)

However, Baxter has waived or forfeited this “concentrations” argument. In its opening brief, Baxter made clear that its position in favor of dismissal here was that the “dissociated bitartrate anions [in its products] nonetheless cannot, as a matter of law, constitute a ‘chelating agent’ within the scope of the Asserted Claims without eliminating a critical claim element.” (D.I. 127 at 14) What Baxter *didn’t* clearly argue in that opening brief was something like: “And even if Nevakar demonstrates that the dissociated bitartrate anions could be equivalent to a ‘chelating agent’ under the FWR or insubstantial differences test, Nevakar’s DOE infringement claims should nevertheless fail because it cannot show that the bitartrate anions are present in the *claimed concentrations*.” Baxter could have made that kind of an argument in its opening brief—it simply failed to do so. (*Id.*) Instead, it put the argument forward for the first time in its reply brief. (Tr. at 69-70 (Nevakar’s counsel noting the same)) That is not permitted, and Baxter has waived or forfeited the argument as a result. *See Sysmex Corp. v. Beckman Coulter, Inc.*, Civil Action No. 19-1642-JFB-CJB, 2022 WL 1786526, at *6 (D. Del. May 26, 2022) (citing cases).

For all of these reasons, Baxter’s invocation of the all-elements rule and the vitiation doctrine is not a reason to grant summary judgment on the Motion as to Nevakar’s DOE-related direct infringement allegations.

b. The specific exclusion rule

Baxter’s next argument regarding the DOE relates to the “specific exclusion” rule. As to that rule, the Federal Circuit has explained that the “concept of equivalency cannot embrace a

structure that is specifically excluded from the scope of the claims.” *Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1335 (Fed. Cir. 2014) (internal quotation marks and citations omitted). Whether a purported equivalent is specifically excluded is a question of law. *Viv Healthcare Co. v. Gilead Scis., Inc.*, 437 F. Supp. 3d 395, 398 (D. Del. 2020). Here, the particular way that Baxter invokes the specific exclusion rule is by further pointing to the maxim that the “scope of equivalents may also be limited by statements in the specification that disclaim coverage of certain subject matter.” *J&M Corp. v. Harley-Davidson, Inc.*, 269 F.3d 1360, 1366 (Fed. Cir. 2001) (*cited in* D.I. 127 at 15); *see also Rembrandt Pat. Innovations, LLC v. Apple, Inc.*, 716 F. App’x 965, 977 (Fed. Cir. 2017) (“Rembrandt cannot recapture under the [DOE] what the specification clearly gives up.”) (*cited in* D.I. 127 at 16); (Tr. at 22).

More specifically, Baxter points to Tables 2 and 3 found in columns 2 and 3 of the common specification; there, the patents are critical of the studies depicted in these tables, explaining how the tables show that “the norepinephrine at ready-to-inject concentrations underwent significant degradation.” ('735 patent, col. 3:15-17) In the Claim Construction MO, the Court noted this evidence. It suggested that here, the patentee seemed to be stating that a solution including norepinephrine itself (and any bitartrate anion that might dissociate from the norepinephrine in solution)—but one that contained no separately added chelating agent—was ultimately “insufficient to provide the purportedly stable formulation claimed.” (D.I. 106 at 11 (quoting D.I. 67 at 15) (internal quotation marks omitted)) This, the Court explained, was one additional piece of evidence (among many) suggesting that the claimed “chelating agent” “must be separately added into the [claimed] composition.” (*Id.*) Invoking the Court’s prior discussion of that issue here, Baxter argues that this specification excerpt demonstrates that “[b]roadening the claims to allow the single ingredient ‘norepinephrine’ to be both the active ingredient and a

‘chelating agent’ is the ‘opposite of’ or ‘inconsistent with’ what the construed Asserted Claims expressly require and what the specification excluded.” (D.I. 127 at 15-16)

But as the Court noted in the Claim Construction MO, while it felt that this specification excerpt provided another hint that Baxter’s claim construction position for “chelating agent” was correct, the excerpt was “not determinative” evidence, in and of itself. (D.I. 106 at 11; *see also* Tr. at 22) This is in part because it is not as if the excerpt amounted to an example of clear and unmistakable disclaimer on the point. Put differently, it is not as if the patent here specifically and explicitly states: “The claimed chelating agent cannot and must never be a dissociated bitartrate anion that separates from the norepinephrine in solution.” (Tr. at 23, 63-64; D.I. 134 at 19) In light of this, the Court cannot conclude, as a legal matter, that this specification excerpt is an example of the patentee *clearly disclaiming* coverage of what Nevakar seeks to capture through its DOE argument. *J&M Corp.*, 269 F.3d at 1366; *see also SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed. Cir. 2001) (explaining that specific disclaimer applies when the specification “specifically identified, criticized, and disclaimed the [asserted equivalent at issue]”); (D.I. 134 at 18 (Nevakar noting that “the specification makes no statement that restricts the invention to a chelating agent that is a separate chemical compound, added to the composition”)).¹³

¹³ An example of a case where there *was* a specific disclaimer in a patent specification—one that made clear that the scope of equivalents had been limited in a particular manner—came in *Dawn Equipment Co. v. Ky. Farms Inc.*, 140 F.3d 1009 (Fed. Cir. 1998). In *Dawn*, a case involving mechanisms used to selectively reposition farm equipment, the patentee argued that the accused device included an equivalent to a claimed means for locking and releasing; to that end, the patentee asserted that the accused device’s “multiple-hole, pinned height-adjustment mechanism” was equivalent to a rotatable shaft, pin and slot mechanism depicted in the patent-in-suit. 140 F.3d at 1016. The Federal Circuit disagreed. It ruled that no reasonable jury could have found infringement under the DOE. *Id.* While the *Dawn* Court explained that this was in part because the patentee’s evidence could not meet the FWR test, it also noted that the patent specification taught that multiple-hole, pinned height-adjustment

Indeed, Nevakar has now come forward with contrary evidence on this same point. On that score, Dr. Anderson notes that a POSITA would “know that the degradation of [the formulations referenced in Tables 2 and 3] is a complex, multi-factorial issue where the degradation could result from a number of causes beside metal ions that may be impacted by the chelator, including for example, uncontrolled pH, light, oxygen and other oxidizing agents, and microbial contamination.” (Anderson Decl. at ¶ 94) In paragraph 95 of his declaration (“paragraph 95”) Dr. Anderson further explained, for example, that prior studies have provided data on the pH of norepinephrine concentrate formulations that were diluted in 250 mL saline (like those described in Tables 2 and 3); in these studies, two concentrations were diluted, which resulted in final concentrations of 4 µg/mL and 16 µg/mL, and the diluted formulations had a pH of 5.0 and 4.5, respectively. (*Id.* at ¶ 95) These pH levels are higher than the range of the claimed formulation of 3.7-4.3, and Dr. Anderson explains that in these higher pH ranges, norepinephrine is increasingly unstable. (*Id.*) Taken together, what Dr. Anderson is suggesting is: (1) although Tables 2 and 3 do not report what the pH levels were of the formulations discussed therein; (2) those formulations are likely similar to those in the prior studies Dr. Anderson described; and (3) so, to the extent the patents criticize the formulations in Tables 2 and 3 as having undergone significant degradation, that degradation could have occurred because

mechanisms, like the one in the defendant’s product, were “time-consuming to adjust and [were] prone to misadjustment . . . [and] are easily lost.” *Id.* The Federal Circuit held that these statements in the patent “strongly suggest, if not mandate, judgment in” the defendant’s favor on the DOE issue. *Id.* at 1016-17; *see also* *J&M Corp.*, 269 F.3d at 1366 (citing to *Dawn* as an example of a case where the “scope of equivalents [was] limited by statements in the specification that disclaim coverage of certain subject matter”). The statements in the patents-in-suit here regarding degradation are simply not as direct or as clear as those in a case like *Dawn*—in terms of their disparagement or exclusion of the claim scope at issue in the DOE analysis (i.e., whether a chelating agent not separately added to the claimed solution could be viable).

the formulations had *higher-than-ideal pH levels* (just like the formulations in the prior studies)—not because of anything having to do with how effective any dissociated bitartrate anions located therein were as a chelating agent.¹⁴ (D.I. 134 at 18 (“[T]his data provides no statement, criticism or conclusion about the tartrate’s efficacy as a chelator, much less about its chelating function.”); Tr. at 52-56; Nevakar’s Hearing Presentation, Slides 4-5)¹⁵ This disputed evidence of fact only further indicates why summary judgment should not be granted to Baxter as to Nevakar’s DOE-related infringement theory.¹⁶

In the Court’s view, then, Baxter’s invocation of the specific exclusion rule is not enough to warrant summary judgment on the DOE infringement issue.¹⁷

¹⁴ Nevakar did not make this argument (at least, not explicitly) during the claim construction phase of the case. (Tr. at 22-23, 49-51) Even if it had, that would not have changed the Court’s view as to the correct claim construction for “chelating agent.”

¹⁵ Nevakar does not dispute that the presence of a chelating agent in the claimed formulation is meant to help stabilize the formulation and to prevent its degradation. (Tr. at 53-55) Indeed, at the *Markman* hearing in this case, Nevakar’s counsel acknowledged that separately added chelating agents described in the specification were being added to formulations in order to “confer stability to the norepinephrine.” (D.I. 86 at 30) But Nevakar’s position is that “you can’t attribute [the results listed in Tables 2 or 3] to any one variable[,]” or draw the conclusion that any significant degradation thereof is due to the lack of a separately added chelator. (Tr. at 53-55)

¹⁶ Baxter argues that this portion of Dr. Anderson’s declaration is not relevant to any real dispute of fact about whether dissociated bitartrate anions can be the equivalent to the claimed chelating agent, because Dr. Anderson provides “no evidence that the pH of the actual product in [Tables 2 and 3] made a difference” to the relevant formulations’ degradation. (Tr. at 24; *see also* D.I. 144 at 19) It is true that in paragraph 95, Dr. Anderson was not citing to any data regarding the actual formulations discussed in Tables 2 and 3. Instead, he was there utilizing formulation data reported in a prior art reference (“Tremblay”), and suggesting that the formulations discussed in Tremblay were similar to the formulations cited in this portion of the patents. From there, he drew certain conclusions about the patents’ formulations. (Tr. at 24-25) In the Court’s view, this type of circumstantial evidence-based argument is something a jury could consider in assessing the DOE issue.

¹⁷ Although Baxter’s two primary arguments as to the DOE issue implicated the all-elements rule and the specific exclusion rule, it did make a third argument in its briefing as to

c. Indirect Infringement

Baxter's Motion also seeks summary judgment that its products do not indirectly infringe any asserted claim. (D.I. 127 at 18) Here, Baxter simply notes that: (1) there can be no indirect infringement without direct infringement; and (2) because its products "do not directly infringe" the asserted claims (for the reasons Baxter asserts in Sections III.B.2.a & b above), Baxter cannot be liable for indirect infringement. (*Id.*; *see also* D.I. 134 at 13; D.I. 144 at 20)

As this portion of the Motion rises and falls with the Court's prior decisions regarding the direct infringement issues, the Court orders that the Motion will be granted-in-part and denied-in-part to the extent it seeks summary judgment on Nevakar's indirect infringement claims. Since summary judgment is not warranted as to Nevakar's claim for direct infringement under the DOE, Nevakar's indirect infringement claims can stand—to the extent they are premised on DOE-related direct infringement allegations.

IV. CONCLUSION

For the reasons set out above, the Court orders that the Motion be GRANTED-IN-PART and DENIED-IN-PART. More specifically, the Motion is: (1) granted as to Nevakar's literal direct infringement claims; (2) denied as to Nevakar's DOE direct infringement claims; and (3) granted-in-part and denied-in-part as to Nevakar's indirect infringement claims (that is, granted

this issue: i.e., that "public policy strongly weighs in favor of the Court's rejection of Nevakar's . . . 'dissociated bitartrate anions' infringement theory." (D.I. 127 at 16) In that regard, Baxter argues that were Nevakar able to use the DOE to "effectively read out" the "chelating agent" claim limitation, this would be legally impermissible, because the "public has a right to rely on the language of patent claims." *Duncan*, 914 F.3d at 1362 (*cited in* D.I. 127 at 16-18). But the "public policy" caselaw that Baxter is invoking simply notes the unremarkable proposition that there are legal limits as to what the DOE can rightly cover. (D.I. 134 at 20) The entire question here is whether Nevakar's DOE arguments extend past those limits. And the answer to that question, as the Court has previously noted above, will depend on a factfinder's analysis of the evidence regarding the applicability of the FWR test and the insubstantial differences test.

only to the extent those claims are premised on literal direct infringement allegations, and otherwise denied).

An appropriate Order will issue.